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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------|------------------|
| 09/939,275 | 08/24/2001 | Christopher P. Adams | EXT-062CN | 3814 |
| 30623 | 7590 | 10/04/2004 | EXAMINER | |
| MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111 | | | SITTON, JEHANNE SOUAYA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1634 | |

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/939,275 | | ADAMS ET AL. | |
| | Examiner | | Art Unit | |
| | Jehanne S Sitton | | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/16/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The examiner reviewing your application at the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Jehanne Sitton.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Currently, claims 1-20, are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

Maintained Rejections

4. The rejection of claims 1, 5, 7, and 19 under 35 USC 103(a) as being unpatentable over Jiro et al in view of Gelfi et al and further in view of Carreira et al made in the previous office action at pages 3-5 is maintained and reiterated herein.
5. The rejection of claims 2-4, 10-14, and 16 under 35 USC 103(a) as being unpatentable over Jiro et al in view of Gelfi et al and further in view of Carreira et al and

Art Unit: 1634

further in view of Cantor et al made in the previous office action at pages 5-7 is maintained and reiterated herein.

6. The rejection of claims 8, 9, 17, and 18 under 35 USC 103(a) as being unpatentable over Jiro et al in view of Gelfi et al and further in view of Carreira et al and further in view of Cantor et al and further in view of Mullis made in the previous office action at pages 7-8 is maintained and reiterated herein.

7. The rejection of claims 6 and 15 under 35 USC 103(a) as being unpatentable over Jiro et al in view of Gelfi et al and further in view of Carreira et al and further in view of Stamato et al made in the previous office action at pages 8-10 is maintained and reiterated herein.

8. The rejection of claim 20 under 35 USC 103(a) as being unpatentable over Jiro et al in view of Gelfi et al and further in view of Carreira et al and further in view of Ghosh et al made in the previous office action at pages 10-11 is maintained and reiterated herein.

Response to Arguments

9. The response traverses the rejection of Jiro et al in view of Gelfi et al and further in view of Carreira et al at pages 8-11. At pages 8-10, the response asserts that the cited references cannot be properly combined because modifying Jiro in view of Gelfi and Carreira would make the method of Jiro unusable for its intended purpose. The response summarizes the teachings at page 6, 2nd para and embodiment 1 of Jiro and states that the

Art Unit: 1634

method of Jiro is dependent on the formation and detection of two separate regions of complementarity in three nucleic acids and that completely denaturing conditions as taught by Gelfi would render Jiro's method unworkable. This argument has been thoroughly reviewed but was found unpersuasive. While it is noted that the characterization of Jiro set forth in the response uses 3 nucleic acids, such characterization ignores the more general method taught by Jiro, for example at page 2, sections 2 and 3. Substituting the method of Gelfi, that is increasing the voltage to dissociate the hybridization complex, with the method of Jiro would not make the method of Jiro unusable. As stated in the previous office action at page 12-13, "It is clear that simply because Jiro et al discusses a preferred embodiment, this embodiment does not prevent the reference from suggesting broader embodiments in the disclosure...". While an embodiment taught by Jiro is dependent on the formation and detection of two separate regions of complementarity, the general method taught by Jiro is not. The situation is therefore not analogous to the issue in *In re Gordon*.

The response further traverses at page 10 that the combination of references cannot be used because modifying Jiro by combining with Gelfi changes the principle of operation of the method of Jiro and cites *In re Ratti* (CCPA 1959). This argument has been thoroughly reviewed by was not found persuasive because the principle of increasing temperature to denature hybridization was introduced in the method of Jiro, and is the same principle as taught by Gelfi, that is applying heat for denaturation. The fact that Gelfi uses voltage to produce ohmic heat for denaturation does not change this principle. No substantial reconstruction of Jiro would be required by the substitution of Gelfi, only that a voltage increase would be the source of denaturing. The rejection sets

Art Unit: 1634

forth that using voltage to produce ohmic heat as taught by Gelfi would minimize the different apparatuses needed to perform the denaturation function, thereby saving material expense, time and effort (see previous office action: page 4, last sentence of first full para).

The response traverses that Carrieria has no teaching that overcomes the non compatibility of Jiro and Gelfi. This argument has been thoroughly reviewed but was not found persuasive for the reasons set forth above, that is that the Jiro and Gelfi references are in fact compatible. For these reasons and the reasons made of record above and in previous office actions, the rejection is maintained.

At pages 11-13, the response traverses each of the remaining rejections made in the previous office action based on arguments made with regard to Jiro and Gelfi. For the reasons made of record above and in previous office actions, the rejections made in the previous office action are maintained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

Art Unit: 1634

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


11. No claims are allowable over the cited prior art.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 7:00 AM to 4:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Jehanne Sitton
Primary Examiner
Art Unit 1634

9/30/04